

Facility Name:
Effective Date:
Reviewed By:

VFC PIN:
Annual Review Date:

## VACCINE STORAGE AND HANDLING PLAN

This vaccine storage and handling plan allows for the to safeguard vaccine supplies and respond to improper vaccine storage and handling events. Providers should consult CDC's Vaccine Storage and Handling Toolkit available at <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf> for the most current guidance and best practices regarding vaccine storage and handling.

### ROUTINE VACCINE STORAGE AND HANDLING GUIDELINES

#### 1. STORAGE REQUIREMENTS

- A. Store all refrigerated vaccines at 36.0° through 46.0°F or 2.0° through 8.0°C. Store all varicella-containing vaccine (Varivax, Zostavax, ProQuad) frozen at -58.0° through +5.0°F or -50.0° through -15.0°C.
  - Proper temperatures for refrigerator(s) and freezer(s) are posted on unit(s) and vaccines are stored per manufacturer guidelines.
- B. Store MMR vaccine in the freezer. Storing MMR vaccine in the freezer with MMRV may help prevent inadvertent storage of MMRV in the refrigerator and may prevent MMR vaccine loss in the event of a temperature excursion. Diluent should NOT be stored in the freezer.
  - MMR vaccine is stored in the freezer.
- C. A digital data logger (DDL) with continuous temperature monitoring, recording capability and a current valid Certificate of Calibration Testing must be placed in the refrigerator and freezer unit. The DDL must be equipped with:
  - A temperature probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand or Teflon)
  - An active temperature display outside the unit(s) which can be easily read without opening the storage unit's door
  - Logging interval (or reading rate) programmed to measure and record temperatures at least every 30 minutes
  - Alarm for out of range temperatures
  - Low battery indicator
  - Current, minimum, and maximum temperature display
  - Recommended uncertainty of +/-0.5 °C (+/-1°F)
 Certificates of Calibration Testing must include:
  - Model/device name or number
  - Serial number
  - Date of calibration (report or issue date)
  - Confirmation the instrument passed testing (or instrument in tolerance)
  - Recommended uncertainty of +/-0.5 °C (+/-1°F)
  - Digital data logger is in place in each unit (both refrigerator and freezer).
- D. A back-up digital data logger with a current and valid Certificate of Calibration Testing is readily available to use if the primary temperature monitoring device breaks.
  - A back-up digital data logger is readily available.
- E. To help stabilize temperatures in the refrigerator, place water bottles on the top shelf, floor, and in the door racks. In the freezer, place water bottles against the walls, in the back, on the floor, and in the door racks. (Water bottles are not recommended to use with certain pharmaceutical grade and purpose built units. For such units, follow manufacturer guidance.)
  - Water bottles are present in the unit(s).
- F. Store vaccine on refrigerator/freezer shelves in manufacturer packaging with lids closed in open containers and away from walls and the back of the unit to allow proper air circulation around the vaccine.
  - Vaccine is stored in center of unit(s) in manufacturer packaging in open containers to allow for air circulation.

- G. Vaccine should never be stored under cooling vents, in the door of the refrigerator, vegetable containers/bins (crisper) or on the bottom of the refrigerator.
  - Vaccine is not stored under cooling vents, in the door of the unit, crisper, or in the bottom of the unit.

## 2. EQUIPMENT/SAFEGUARDS

- A. Vaccines should be stored in a purpose-built, pharmaceutical/medical grade or household-grade stand-alone or combination unit with enough room to store the largest inventory a provider might have at the busiest point in the year without crowding. These units may vary in size from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit.
- B. Dorm-style refrigerator/freezers with a cooling plate and an internal door to a freezer compartment are not allowed for the storage of vaccines.
- C. If using a combination household refrigerator/freezer unit, only use the refrigerator compartment for storing refrigerated vaccines. A separate stand-alone freezer should be used to store frozen vaccines.
  - Vaccines are stored in appropriate storage unit(s).
- D. New and repaired storage units are stable and ready to store vaccines when temperatures are maintained within the recommended range for 2 consecutive days.
- E. Post warning signs on the storage unit and at the outlet to prevent inadvertent unplugging of the unit.
  - Warning signs (e.g., Do Not Unplug) are posted on vaccine storage units and at the outlet.
- F. Label fuses and circuit breakers to clearly identify power sources to the vaccine storage unit.
  - Fuses and circuit breakers supporting vaccine storage units are clearly marked.
- G. Do not plug unit into ground fault interrupter (GFI) outlets. When the GFI is tripped the circuit is broken, causing electricity failure to the unit. Do not use an extension cord or power strip to plug in the storage unit.
  - The vaccine storage unit is not plugged into a GFI outlet, extension cord or power strip.
- H. Ensure doors are shut tightly.
  - Doors close securely and are free from defect.

## 3. TEMPERATURE MONITORING

- A. A digital data logger should be present in each unit (both refrigerator and freezer). See 1. C. Place the buffered probe of the DDL in the center of the unit with the vaccines surrounding it.
  - Digital data logger is in place in each unit (both refrigerator and freezer).
- B. Place the DDL's active digital display on the outside of the unit so temperatures can be checked without opening the door and disturbing the probe. DDLs should be set at a minimum recording interval of at least every 30 minutes.
- C. A back-up digital data logger is readily available to use if the primary temperature monitoring device breaks. See 1. D.
- D. The designated person checks and records min/max refrigerator and freezer temperatures at the start of each work day and records the time and name/initials associated with each temperature reading.
- E. The designated person checks and records refrigerator and freezer temperatures twice daily (at the beginning and end of each work day) and records the time and name/initials associated with each temperature reading.
- F. Storage temperatures should be recorded on a temperature log and maintained for at least 3 years. This is useful to identify the duration of temperature variations. If a digital data logger has the capability to annotate an electronic temperature check with the time and initials of the person checking the temperature, it is not necessary to manually log the temperature checks at each temperature check.
  - Refrigerator and freezer min/max temperatures are checked and recorded on a temperature log at the start of each work day along with staff initials and time of reading.
  - Refrigerator and freezer temperatures are checked and recorded on a temperature log twice daily along with staff initials and time of readings. Storage temperature logs are maintained for at least 3 years for each unit either in electronic or paper format.

- G. If a temperature outside of the recommended range is found, immediate action should be taken as outlined in the Emergency Vaccine Storage, Handling, and Transport Guidelines. Actions taken should be documented on the [Vaccine Storage Troubleshooting Record](#).
- Clinic staff is trained to take immediate action if temperatures are out of range.
- H. The designated person should review the temperature log at least weekly to ensure proper temperature recording and take action if out of range temperatures are found on the logs during review. Digital data logger data should be downloaded and reviewed every two weeks. Data must be maintained for at least three years in electronic or paper format.
- The designated person reviews temperature logs at least weekly.
  - The data logger is downloaded and reviewed every two weeks and whenever the data logger alarms.
- I. Consideration should be given to how power failures or out of range temperatures will be identified during non-business hours.

#### 4. VACCINE ORDERING

Health care providers participating in the Vaccine For Children (VFC) Program are responsible for ordering and maintaining adequate vaccine inventory for eligible patients to prevent missed opportunities. The Iowa Department of Public Health, VFC Program requires VFC providers to place vaccine orders using the Immunization Registry Information System (IRIS). IRIS contains vaccine order functionality which includes recommended order quantities based on ordering patterns and doses administered data. When placing vaccine orders, review recommended order quantities for each vaccine and total amount of vaccine needed including combination and single antigen products.

- Review current inventory/expiration dates and consider seasonal events or specialty clinics.
- Clinic staff is aware of Economic Order Quantity.
- Clinic staff is trained regarding vaccine ordering.
- Do not over-order or stockpile vaccine.
- Maintain adequate inventory of VFC and private vaccine (if applicable) to eliminate occurrences of borrowing between VFC and private inventories.

#### 5. RECEIVING VACCINE

Develop and post a protocol for accepting vaccine deliveries that indicates who in the practice may accept vaccine shipments to ensure vaccines are stored appropriately and **IMMEDIATELY** after arrival. Train staff how to compare the vaccine received with the vaccine invoice.

Cold and heat indicators should be reviewed immediately to ensure vaccine was maintained at the appropriate temperatures during shipping. Alert the VFC Program at 1-800-831-6293 if the vaccine is not in proper condition, the number of doses differ from the invoice, the lot number is recorded incorrectly on the invoice, or the vaccine and diluent expiration dates indicate expired or soon-to-expire products.

- Protocol is posted for all staff regarding vaccine deliveries and whom to contact regarding vaccine shipments.
- Clinic staff ensure vaccine shipments are stored properly immediately upon arrival.
- Clinic staff is trained how to compare vaccine received to the vaccine invoice and will alert the VFC Program if vaccine doses do not match the invoice or if they are not in proper condition upon arrival.
- Maintain vaccine packing slips for both VFC and private vaccine inventory for a minimum of three years.

## 6. VACCINE MANAGEMENT/STOCK ROTATION

Check and rotate stock monthly and when new vaccine inventory arrives. Ensure vaccines with the most current expiration dates are used first and are in front of vaccines with longer expiration dates.

- Conduct count of vaccine inventory at least monthly.
- Rotate vaccine stock regularly; move earliest expiration dates to the front.
- Check vaccine expiration dates at least monthly. Remove expired vaccines immediately.
- Clinic staff is able to distinguish VFC vaccine from private vaccine.
- Report VFC vaccine that will not be used and will expire within 2-3 months to the Iowa VFC Program at 1-800-831-6293.

## 7. STAFFING/TRAINING

Post the Vaccine Storage and Handling Plan on or near the vaccine storage units and ensure all staff are trained regarding the plan. Review current guidelines for handling of individual vaccines that may include special instructions (e.g., protect from light, shelf life after reconstitution). Understand package inserts for new vaccines before using. Additional references include the Centers for Disease Control and Prevention (CDC)'s "You Call the Shots, Vaccine Storage and Handling" available at <http://www.cdc.gov/vaccines/ed/youcalltheshots.html>

- Vaccine Storage and Handling plan is posted on or near storage unit.
- All staff is trained on the plan and training is documented (minimum of annually).
- Staff is trained on guidelines for handling individual vaccines with special instructions.
- Staff who administers vaccine have read and understand package inserts prior to administering vaccine.
- Staff has access to manufacturer's package inserts for each vaccine on hand and the CDC Epidemiology and Prevention of Vaccine Preventable Diseases (Pink book).

## 8. DESIGNATED PERSON(S)

Designate a primary and a backup person to:

- Monitor the operation of the vaccine storage units and systems.
- Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that would create an interruption of power.
- Ensure the appropriate handling of the vaccine during a disaster or power outage.
- Ensure access to the building where vaccines are stored 24 hours per day.

Primary Person:	Phone:
Secondary Person:	Phone:
Additional Staff:	Phone:
IDPH Regional Immunization Nurse Consultant:	Phone:
Iowa Immunization Program:	Phone: 800-831-6293

## 9. BACK-UP SUPPLIES/FACILITY

It is important to have a back-up plan to appropriately store vaccine. Make formal arrangements (memorandum of understanding) with a backup facility to maintain vaccine if vaccine storage equipment malfunctions or there is a power outage. Train a designated person and backup person at the facility to accept vaccine if it must be moved. Before moving vaccine, call the location to ensure the facility is available to store the vaccine (e.g., not damaged due to storms). If the back-up facility is not available contact the other facilities on the backup facility list.

### BACK-UP FACILITIES CONTACT INFORMATION

Name of Facility	Primary/Back-up Contact	Contact Phone Number Work/Home/Cell

Facilities should have a sufficient supply of materials needed for vaccine transport of the largest inventory at any given time. Reference ['Packing Vaccines for Transport during Emergencies'](#)

Appropriate materials include:

- Portable vaccine refrigerator/freezer units (preferred option)
- Qualified containers and packouts
- Hard-sided insulated coolers or Styrofoam (This system should only be used in an emergency)
- Coolant materials such as phase change materials (PCMs) or conditioned frozen water bottles
- Insulating materials such as bubble wrap and corrugated cardboard-enough to form two layers per container
- DDLs for each container

### EMERGENCY CONTACT LIST

List of emergency phone numbers, companies, and points of contact:

<input type="checkbox"/> Electric Power Company:
<input type="checkbox"/> Temperature Alarm Monitoring Company:
<input type="checkbox"/> Refrigerator Repair Company:
<input type="checkbox"/> Transportation to Back-up Storage:
<input type="checkbox"/> Emergency Generator Repair Company:
<input type="checkbox"/> National Weather Service:

### FACILITY FLOOR PLAN

Entering vaccine spaces: Describe, when necessary, how to enter the building and vaccine storage spaces in an emergency if closed or after hours. Include a simple floor diagram (does not need to be a blue print) and the locations of:

<input type="checkbox"/> Storage units:
<input type="checkbox"/> Doors:
<input type="checkbox"/> Flash lights:
<input type="checkbox"/> Spare batteries:
<input type="checkbox"/> Light switches:
<input type="checkbox"/> Keys:
<input type="checkbox"/> Locks:
<input type="checkbox"/> Alarms:
<input type="checkbox"/> Circuit breakers:
<input type="checkbox"/> Packing materials:

## EMERGENCY VACCINE STORAGE, HANDLING, AND TRANSPORT GUIDELINES

### 1. RESPONSE TO IMPROPER VACCINE STORAGE AND HANDLING/TEMPERATURE EXCURSION ASSESS THE SITUATION

- A. Determine the cause of improper vaccine temperatures (e.g., mechanical failure, power outage, natural disaster, human error).
- B. Store the vaccines at appropriate temperatures. Determine if vaccine should be moved and move if appropriate.
- C. Mark the vaccine "Do Not Use" so the potentially compromised vaccines can be easily identified and not used until viability of vaccine is determined.
- D. Record the current temperature of the refrigerator/freezer. Download the data logger.
- E. Collect essential data on the Emergency Vaccine Response Worksheet.
- F. Call the Iowa Immunization Program (1-800-831-6293).
- G. Call all manufacturers of affected vaccine(s).

### 2. PACK VACCINE FOR RELOCATION TO AN ALTERNATE STORAGE UNIT IF NEEDED

Consult 'Packing Vaccines for Transport during Emergencies' (CDC) handout:

<https://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf>

- A. Open storage units only when absolutely necessary and only after all preparations have been made for packing and moving the vaccine to alternative storage site.
- B. Use hard sided coolers with at least 2 inch walls, or portable refrigeration units, to transport vaccine supply.
- C. Refrigerated vaccines: frozen water bottles can be used as coolant packs if properly conditioned. Hold water bottles under running tap water or submerge in a sink filled with tap water until a layer of water forming near the surface of the plastic can be seen. Once the ice block inside the the bottle can spin freely, the bottle is ready to be used for packing. Use appropriate insulating materials (e.g., bubble wrap) to protect vaccines from direct contact with the water bottles. Do not use frozen gel packs or coolant packs from vaccine shipments to pack refrigerated vaccines.
- D. Frozen vaccines: the manufacturer of varicella-containing vaccines, Merck, recommends the vaccines (Varivax, Zostavax, ProQuad) **NOT** be transported on dry ice. Use of dry ice may subject the vaccines to temperatures colder than -58.0° F (-50.0° C). Several companies make portable freezer units. **NOTE:** In the event the vaccine must be moved due to emergency situations and a portable freezer unit is not available, Varicella-containing vaccine should be moved in a separate cooler from the refrigerator vaccines. The cooler containing varicella vaccines should be packed with as many ice packs as possible and place a data logger in the cooler. The time and temperature must be monitored and recorded until vaccine is stored under proper conditions in an approved storage unit. Once the vaccine has been stored appropriately contact the Iowa Immunization Program and the manufacturer prior to using the vaccine.
- E. Include a data logger with a certificate of calibration with the vaccine in each cooler to monitor the vaccine temperature during transport. It is recommended a digital data logger with a detachable probe in a buffered material be used so temperature readings can be obtained during transport without opening the container.

### **3. MOVE VACCINE**

- A. If alternative storage is available within the facility, transfer vaccine to that storage unit. If not, contact the backup facility to notify them of a refrigerator/freezer failure and the need to store vaccine at the backup location.
- B. Prior to transporting vaccine, record the time and the temperature of the refrigerator(s) and freezer(s) units. This will provide data on the maximum temperature and duration of exposure of vaccine to inappropriate temperatures.
- C. Conduct an inventory count before vaccine is transported.
- D. Transport the vaccine following proper cold chain procedures for storage and handling.
- E. Isolate and maintain vaccines at appropriate temperatures and do not administer or discard vaccine until the Iowa Immunization Program (1-800-831-6293) has been contacted for consultation. Download the data logger utilized during the transport.

### **4. POST EVENT**

Keep exposed vaccine separated from unaffected vaccine and any new vaccine received. Maintain vaccines at appropriate temperatures and do not administer or discard any potentially exposed vaccine until the Iowa Immunization Program (1-800-831-6293) has been contacted for consultation. Download the data logger(s) from the affected storage unit(s) as soon as possible. This will provide additional details around the excursion event including the actual temperatures and timeframe the vaccine was exposed to out of range temperatures.

### **5. VACCINE WASTAGE**

Never assume vaccine is nonviable in the event of a storage problem or handling issue. Contact the Iowa VFC Program immediately (1-800-831-6293) for instructions regarding VFC vaccine. Vaccines determined to be non-viable should be removed from storage units to avoid unintentional use and labeled as "Nonviable Vaccine-Do Not Use". VFC providers using IRIS inventory shall document vaccine loss using appropriate reasons provided in the registry to deduct doses from inventory.

For IRIS non-inventory providers, expired and spoiled vaccine shall be reported on the [Nonviable VFC Vaccine Return Form](#) and faxed to the VFC Program at 1-800-831-6292. Expired and wasted vaccines should be returned to McKesson; refer to the [VFC Non-viable Vaccine Return Form](#) for instructions.

## EMERGENCY VACCINE RESPONSE CONTACT LIST

*Post on outside of refrigerator*

### Vaccine Storage and Handling Staff:

Primary:	Phone:
Secondary:	Phone:
Staff with 24 hour access:	Phone:
Additional Staff:	Phone:
IDPH Regional Immunization Nurse Consultant:	Phone:
Iowa Immunization Program:	Phone: 800-831-6293

### Emergency Contact List:

Backup Storage Facility:	Phone:
Backup Storage Facility:	Phone:
Electric Power Company:	Phone:
Refrigerator Repair Company:	Phone:
Temperature Alarm Monitoring Company:	Phone:
Transportation to Backup Storage:	Phone:
Emergency Generator Repair Company:	Phone:
National Weather Service:	Phone:
Fuel for Generator:	Phone:

### Vaccine Storage and Handling Events:

1. Determine the cause of improper vaccine temperatures (e.g., mechanical failure, power outage, natural disaster, human error).
2. Store the vaccines at appropriate temperatures. Determine if vaccine should be moved and move if appropriate.
3. Record the current temperature of the refrigerator/freezer.
4. Mark the vaccine so the potentially compromised vaccines can be easily identified and not used until viability of vaccine is determined.
5. Collect essential data on the Emergency Vaccine Response Worksheet (attach additional copies if necessary).
6. Call the Iowa Immunization Program (1-800-831-6293).
7. Call all manufacturers of affected vaccine(s).

# EMERGENCY VACCINE RESPONSE WORKSHEET

Facility Name: \_\_\_\_\_ VFC PIN: \_\_\_\_\_

Date of event: \_\_\_\_\_ Handling Error: \_\_\_\_\_

Current refrigerator temperature: \_\_\_\_\_ °F/°C Min/Max (Circle) refrigerator temperature reached: \_\_\_\_\_ °F/°C

Current freezer temperature: \_\_\_\_\_ °F/°C Min/Max (Circle) freezer temperature reached: \_\_\_\_\_ °F/°C

Total length of time temperature was outside normal range for refrigerator: \_\_\_\_\_ or freezer: \_\_\_\_\_

REFRIGERATOR	Vaccine/Manufacturer	Lot Number	Expiration Date	Number of Doses	Opened Vials	Manufacturer Recommendations	

FREEZER	Vaccine/Manufacturer	Lot Number	Expiration Date	Number of Doses	Opened Vials	Manufacturer Recommendations	

VACCINE MANUFACTURERS	Vaccine	Manufacturer	Phone
	IPV, Daptacel, DT (Generic), Tenivac, ActHib, Fluzone, Flublock RIG, Imovax, Typhim Vi, YF-VAX, Adacel, Menactra, Pentacel, Tubersol, Quadracel	Sanofi Pasteur	1-800-822-2463
	Recombivax HB, MMR, Varivax, PedvaxHIB, Pneumovax 23, Vaqta, RotaTeq, Gardasil, Zostavax, ProQuad	Merck	1-800-444-2080
	Infanrix, Pediarix, Enderix B, Havrix, Twinrix, Boostrix, Fluarix, Kinrix, Rotarix, FluLaval, Hiberix, Bexsero, Menveo, RabAvert, Shingrix	GlaxoSmithKline	1-877-356-8368
	Prevnar13, Trumenba	Pfizer	1-800-438-1985
	Td (Generic)	MassBiologics/Grifols	1-888-474-3657
	Immune Globulin	Grifols	1-888-474-3657
	Nabi HB (Hep B Immune Globulin)	Nabi	1-800-458-4244
	Synagis, Flumist	MedImmune	1-877-633-4411
	Flucelvax, Afluria, FLUAD	Seqirus	901-432-3920
	Vivotif (typhoid), Vaxchora	PaxVax	1-888-533-9053
	Hepelisav-B	Dynavax Technologies	1-877-848-5100
Aplisol	JHP Pharmaceuticals LLC	248-651-9081	

